



EPA Enforcement

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Herb Estreicher



Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in *Who's Who Legal: Environment* and in *Marquis Who's Who in America*. Herb holds a PhD in Chemistry from Harvard University (1980) in addition to his U.S. law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in *Inside EPA*, *Chemical Watch*, and *BNA Environmental Law Reporter*. He is one of the few U.S.-based lawyers that is expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.

Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.

Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.



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Thomas C. Berger



Thomas C. (Tom) Berger has a chemical engineering background and is a partner at Keller and Heckman. His practice focuses on the regulation and approval of new and existing chemicals under the Toxic Substances Control Act (TSCA) and its international counterparts. Mr. Berger also counsels trade association clients on various matters, including environmental, and product disparagement and defense issues. Mr. Berger has been heavily involved in “reformed” TSCA, EPA's Chemical Data Reporting (CDR) rule, TSCA “Work Plan Chemicals,” and the TSCA Inventory “reset.”



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EPA Office of Administrative Law Judges



- ◆ The Office of Administrative Law Judges (OALJ) is an independent office in EPA's Office of Mission Support.
- ◆ The Administrative Law Judges (ALJs) conduct hearings and render decisions in among other things EPA civil penalty cases.
- ◆ Decisions issued by an ALJ are subject to review by the EPA Environmental Appeals Board (EAB).
- ◆ The final Administrative Order to Pay the Civil Penalty is appealable within 30-days to the U.S. Court of Appeals for the DC Circuit or in any Circuit where the Respondent resides or transacts business.

Anatomy of an Enforcement Case

- ◆ EPA will typically issue a Notice of Violation (NOV) and invite settlement discussions (*Tom will discuss*).
- ◆ If no settlement, EPA files a complaint with an EPA Presiding Officer (who is either an ALJ or a Regional Judicial Officer).
- ◆ The Presiding Officer compiles an administrative record which may include an oral hearing and the taking of expert testimony.
- ◆ The losing party can appeal the decision of the Presiding Officer to the EAB within 30 days.
- ◆ An EAB panel reviews the administrative record, the written pleadings and, in some cases, holds oral argument. The EAB then issues a final written decision.
- ◆ Within 10 days of a final written decision, any party can file a motion seeking reconsideration of the EAB decision.

Statistics

- ◆ Since 2016, only 19 TSCA cases brought before an ALJ. Most settle prior to a hearing.
- ◆ Most TSCA inspections focus on low-hanging fruit, i.e., failure to report for the CDR or failure to submit 12(b) notices. Amount at issue does not justify the transactions costs of going to an ALJ or beyond. Also - there may not be a colorable legal claim or facts in dispute.
- ◆ But what if the amount at issue is in the millions?
- ◆ Or a company faces an existential threat?

Federal Court Review

- ◆ Standard of Review Arbitrary, Capricious, or **Contrary to Law**.
- ◆ Court review of the Administrative Decision will focus on procedural irregularities or legal error.
- ◆ 1984 *Chevron* Decision – Courts must defer to an agency’s reasonable interpretation of ambiguous **legislative** language.
- ◆ 2024 *Loper* Decision – The U.S. Supreme Court held that *Chevron* was overruled. Judicial deference to an agency’s legal interpretation under *Chevron* was incompatible with the courts' fundamental duty to interpret the law.

What about an Agency's Interpretation of its own regulations?

- ◆ *Kisor v. Wilkie* (2019) remains good law. A Court will defer:
 1. Where the regulation is “genuinely ambiguous” after applying all “traditional tools” of interpretation.
 2. The agency’s interpretation of the ambiguous provision must be “reasonable.”
 3. Court must then engage in “an independent inquiry into whether the character and context of the agency interpretation entitles it to controlling weight.” i.e.,
 - a) The agency’s regulatory interpretation “must be the agency’s ‘authoritative’ or ‘official position,’ rather than any more ad hoc statement not reflecting the agency’s views.”
 - b) The “agency’s interpretation must in some way implicate its substantive expertise.”

Can you get a Jury Trial in Court?

- ◆ If you bypass the ALJ (or convince the ALJ to suspend the Administrative Proceeding until the Court rules), you may be able to get a U.S. District Court to grant a jury trial.
- ◆ *SEC v. Jarkesy* (2024) – when the Securities Exchange Commission seeks civil penalties against a defendant for securities fraud, the Seventh Amendment entitles the defendant to a jury trial and thus SEC must bring the action in federal court.
- ◆ Some read *Jarkesy* broadly to apply to all cases where an agency seeks a civil penalty.
- ◆ Others read *Jarkesy* more narrowly arguing that the claim must parallel a “suit at common law.”

Does *Jarkesy* Apply to TSCA Civil Penalty Cases?



- ◆ *Atlas Roofing* (1977) validated OSHA's use of ALJs in workplace civil penalty cases.
- ◆ The *Jarkesy* court did not overrule *Atlas Roofing* but eviscerated it. For the majority, *Atlas Roofing* was a dubious decision at best, all but overruled by subsequent cases, and criticized by the numerous authors of law review articles and treatises cited in a lengthy footnote to the majority's opinion.
- ◆ Questionable whether EPA would be willing to tests whether it can pin its hopes on *Atlas Roofing*. It just settled a TSCA penalty case (*Ro-Cher Enterprise v. EPA*) where the company asked for a jury trial.

TSCA Inspections (§11)

◆ Who

- ◆ Typically, EPA Region (not HQ), will send email or letter setting forth below
 - Subpoena can be used, but infrequent

◆ What

- ◆ Typically documents (not processes/samples) – some required to be provided before inspection, some during, and often some after (CDX)

◆ When

- ◆ Normally few weeks after letter/email, business hours, often ½ day or so

◆ Where

- ◆ Sites typically chosen at random, but sometimes sites in close proximity

◆ Why

- ◆ Assess compliance with TSCA §§ 4, 5, 6, 8, 12, and 13

TSCA Inspections (cont.)

◆ ***Sometimes but not always EPA will:***

◆ **Issue “Site Inspection Report”**

- Complete and factual record of inspection process from opening to closing
- Contain sufficient information re facility/inspection to allow enforcement decisions and develop case (*“it should **never** make conclusions on violations”*).

◆ **Issue an “Opportunity to Show Cause” (sometimes styled “Notice of Potential Violation(s)”)**

- Summary of potential violations
- Opportunity to argue/explain why EPA should not take enforcement action

◆ **Entertain meetings/calls to discuss, compromise, or settle**

- FRE408

Section 16 – Penalties

- ◆ **Civil** – strict liability
 - ◇ Up to \$48,511^(*) per day, per violation
 - * *As of January 2024; subject to mandatory annual adjustment*
- ◆ **Criminal** – knowingly or willfully
 - ◇ Monetary penalties, imprisonment up to one year
- ◆ No explicit **statute of limitations**, but...
 - ◇ *See 3M v. Browner* (D.C. Cir. 1994) (§§5,13)
 - 5 years from when violation “accrued”
 - *n.b.* - some violations are deemed “continuing violations”
 - ◇ *See Elementis Chromium* (EAB 2015 (TSCA §8(e)))

Enforcement Response Policies (ERPs)



- ◆ EPA ERPs – Statute-specific (TSCA, FIFRA, CERCLA, *etc.*)
- ◆ TSCA ERPs – Specific to different provisions of statute
 - ◆ §4 – 1986
 - ◆ §5 – 1989
 - ◆ §§8, 12, 13 – 1999
 - ◆ Others: GLP, PCB, Asbestos

<http://www.epa.gov/enforcement/waste-chemical-and-cleanup-enforcement-policy-guidance-and-publications>

- ◆ **“Gravity-Based Penalty (GBP)”**
 - ◇ **“Nature”** – (1) chemical control, (2) data gathering, (3) hazard assessment
 - ◇ **“Circumstance”** – levels 1 to 6
 - Probability harm will result from violation
 - Per day vs. one day
 - ◇ **“Extent”** – (1) minor, (2) significant, (3) major
 - Batch size for PMN violations:
 - <750 lb = minor
 - 750–7,500 lb = significant
 - >7,500 lb = major

Current Base Penalty Amounts – Section 5



Circumstance “Level”	Extent		
	Major >7,500 lbs.	Significant 750–7,500 lbs.	Minor < 750 lbs.
LEVEL 1 A § 5(e) or § 5(f) order would have been issued; and the substance was further processed or distributed	\$48,511	\$32,987	\$9,702
LEVEL 2 A § 5(e) or § 5(f) order would have been issued; but substance <u>not</u> further processed or distributed	\$38,809	\$25,226	\$5,821
LEVEL 3 A § 5(e) or § 5(f) order would <u>not</u> have been issued; and the substance was further processed or distributed	\$29,106	\$19,404	\$2,911
LEVEL 4 No further processing/distribution nor § 5(e) or § 5(f) order issued; or substance meets “polymer exemption” criteria but was further processed, distributed, or released into environment	\$19,404	\$11,643	\$1,940
LEVEL 5 Substance meets “polymer exemption” criteria and was not further processed, distributed, or released into environment	\$9,702	\$5,821	\$970
LEVEL 6 Early/late NOC (< 30 days early/late) [all considered “major”]	\$3,881	\$2,523	\$388

Common Penalty Examples

- ◆ (1) Manufacture of substance not on Inventory = **\$32,987 per chemical per day of manufacture** (level 1, significant)
 - ◆ Substance would have been §5(e) regulated, was distributed, 750-7500 lb./batch
 - ◆ If imported, for each import day also §13 penalty capped at level 3, significant (**\$19,404/day**)

- ◆ (2) Failure to submit §12(b) export notice = **\$11,643 per chemical per country** (usually only for first export to country (level 4, significant))

- ◆ (3) Failure to report for §8(a) CDR = **\$32,987 per chemical per site** (level 1, significant)

EPA “Audit Policy”

- ◆ *Incentives for Self-Policing: Discovery, Disclosure, Correction, and Prevention of Violations*
 - ◆ 65 Fed. Reg. 19,618 (Apr. 11, 2000)
<http://www.gpo.gov/fdsys/pkg/FR-2000-04-11/pdf/00-8954.pdf>
- ◆ EPA will waive all gravity-based penalties if all nine (9) conditions satisfied
- ◆ EPA will waive 75% GBP if last 8 conditions are met
- ◆ EPA retains right to recover any economic benefit
 - ◆ EPA has stated it plans to focus on “illegal profits”
- ◆ Can use written agreement under NOP
- ◆ **Works extremely well for TSCA violations**

Trends and Continuing Focus Areas

- ◆ Protracted case resolution
 - ◇ “Tolling” agreements
- ◆ R&D exemption, revisited
 - ◇ Robust records = essential
- ◆ CDR – failure to report, PV errors
- ◆ Failure to submit §12(b) notices
 - ◇ Easy to prove/enforce
- ◆ TSCA §20(a) NGO actions (CEH, *et al.*)
 - ◇ *“any person may commence a civil action ... against any person ... who is alleged to be in violation of this chapter or any rule promulgated under section 2603, 2604, or 2605 of this title ... to restrain such violation”*
 - Plastic containers
 - 2020 CDR



Please join us at 10:00 AM Eastern U.S.
Wednesday, August 28, 2024
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, July 24, 2024
www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, August 14, 2024
www.khlaw.com/TSCA-3030

Register Now!

A promotional banner for a Keller & Heckman event. The background features a laboratory setting with test tubes containing colored liquids (blue, red, pink) and a pipette. On the left, there is a molecular model with blue and white spheres. The text is centered and reads: Keller & Heckman logo, **NAVIGATING TSCA: BASICS AND BEYOND 2024**, **NOVEMBER 14-15, 2024**, and **RENAISSANCE ARLINGTON CAPITAL VIEW HOTEL**.

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**NAVIGATING TSCA:
BASICS AND BEYOND 2024**

NOVEMBER 14-15, 2024
RENAISSANCE ARLINGTON
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Thank You

Any questions?



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